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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,912

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Wei Hu

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

06/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,912	Applicant(s) HU, WEI	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-47 is/are pending in the application.
4a) Of the above claim(s) 6-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 41-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amended dated 24 March 2008 has been received. Claims 3-5 have been canceled. Claims 6-40 have been withdrawn. Claims 46-47 have been added. Claims 1-2 and 41-47 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 recite a plurality of distinct carrier pads comprising *water-impermeable* material which contradicts claim 1 from which it depends. Claim 1 recites that the carrier pad is formed of a *permeable* material.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2 and 41-75 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buechler (US 2002/0086436).

Buechler discloses assay devices comprising a sample addition zone, a sample addition reservoir, a sample reaction barrier (e.g. bridging pad), a reaction chamber, a time gate (e.g. wettable barrier), a diagnostic element (e.g. detection zone), and a used reagent reservoir. The devices are comprised of capillary channels which are formed when a top member is placed on the bottom member. See page 4, paragraph [0061] and figure 1. Buechler discloses the sample receiving means and the deposition means can be ports of various configurations, i.e. round, oblong, square or trough in the device. See paragraph [071]. Buechler teaches all necessary reagents for an immunoassay dried into the appropriate element of the device. Buechler specifically teaches that dipstick-type membrane may be incorporated into the device. See page 11, paragraph [0114] and page 14, paragraph [0135]. Although Buechler does not call his zones "pads", they are seen to be same because Buechler specifically teaches that dipstick-type membrane can be incorporated into the device, in which case, they would be equivalent to "pads". Even though Buechler does not specifically state that the width of the sample is larger than the width of the detection zone, it can clearly be seen in Figure 1 that the width of the sample deposition means (1) is larger than the width of the diagnostic element (6), where w=the measurement in the direction of liquid flow or w=the measurement in the direction transverse to the direction of liquid flow. Buechler also does not specifically

state that the width of the bridging pad (time gate 5) is narrower than the length of the sample band, one can clearly see from figure 1 and associated description that the width of time gate (5) is indeed, narrower than the length of the sample band, where w is defined in the direction perpendicular of fluid flow. Therefore, absent unexpected or improved results, the instant device is seen to be anticipated by or obvious over the device of Buechler.

Response to Arguments

6. Applicant's arguments filed 24 March 2008 have been fully considered but they are not persuasive.

Applicant argues that Buechler does not anticipate the instant claims because the device of Buechler does not use bibulous or porous material such as membranes and the like as substrate for the immobilization of reagents or to control the flow the reagents through the device. Applicant also argues that it is improper to combine references where the references teach away from their combination.

These arguments are not persuasive. Buechler specifically teaches at paragraph [0135] devices incorporating *porous members*, such as *membranes* to deliver precise volumes of reagents to the *porous member*. The time gate is also used in conjunction with devices incorporating *porous members*. The fluid control means can also be used in devices incorporating *porous members* to control the rate of flow of reagents through the *porous member*. Even though Buechler teaches preferred embodiments that do not

include the porous members, in no way does Buechler teach that the use of porous members would be detrimental to the operation of the device. Specifically, Buechler teaches how porous members may be used in the device as evidenced above. The argument that Buechler teaches away from the instant invention is not obvious. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be lead in a direction divergent from the path that was taken by the application....[I]n general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Buechler would not have deterred the skilled artisan from using permeable materials in the device as taught. Buechler clearly teaches devices incorporating porous membranes as discussed in paragraph [0135] of the reference. Thus, one of skill in the art would not be deterred from including porous membranes in the device of Buechler.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
June 15, 2008